K002839

OCT - 4 2001

Fisher & Paykel Healthcare Ltd
15 Maurice Paykel Place
East Tamaki
P O Box 14 348
Panmure, Auckland
New Zealand
Telephone: +64-9-574 0100
Facsimile: +64-9-574 0158

21 September, 2001

510(k) Summary of Safety and Effectiveness Information

Model No. / Name: **RT020 End Expiratory Filter**

Classification Name: Breathing Circuit Bacterial Filter - 73 CAH
Anesthesiology Devices, 21 CFR §868.5260 (Class II)

Predicate Device: Intersurgical Inc, 1844 Clear-Guard II Breathing Filter, K990949

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) - (a)(3) Refer to information above and concluding this summary.

(a)(4) Description of the Device

The RT020 End Expiratory Filter is a Breathing Circuit Bacterial Filter according to 21 CFR §868.5260. It is placed at the end of the expiratory breathing tube to prevent transfer of nebulised drug aerosols, pathogens, and other particulate matter to the ventilator and surrounding environment.

The RT020 Filter has a translucent thermoplastic enclosure with dimensions of 78mm long × 67mm maximum diameter, and weighs 21g. It has standard 22mm male and female connector ports with 1:40 conical tapers. It uses an electrostatic, hydrophobic, depth-type filter media.

(a)(5) Statement of the Intended Use

The RT020 Filter is intended to remove microbiological and particulate matter from the gases in a breathing circuit to lessen their impact on the ventilator and surrounding environment. It is positioned at the end of the expiratory limb of a breathing circuit.

(a)(6) Technological Characteristics Summary

The technological characteristics of the RT020 End Expiratory Filter are equivalent to the predicate device listed above. It is equivalent in terms of type (depth-type filter medium), materials (thermoplastic housing), configuration (aligned connector ports with perpendicular filter media) and performance (filtration efficiency, pressure drop).

(b)(1) Discussion of the Non-Clinical Tests

Non-clinical testing of the RT020 End Expiratory Filter has been carried out covering parameters of filtration efficiency, gas leakage, pressure drop, connector sizing, and condensate accumulation.

The proposed device meets the requirements of FDA-recognized medical equipment standards for connector compatibility (ISO 5356-1, ASTM F1054) and applicable performance requirements for filtration efficiency, gas leakage and pressure drop from other standards (MIL-M-36954C, prEN 13328-2,ISO 9360-1).

(b)(2) Discussion of the Clinical Tests

Clinical verification studies on the RT020 End Expiratory Filter were carried out in order to demonstrate that the device operated safely and effectively, and performed acceptably, in a clinical setting.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

- ◊ The intended use and application of the RT020 Filter is within the scope of the intended use and application of the predicate device.
- ◊ There are no features of the RT020 Filter which lead to significant differences in safety, effectiveness or intended use from the predicate device.
- ◊ The testing carried out on the RT020 Filter demonstrates that it meets design and performance functional requirements.

This information indicates that the RT020 End Expiratory Filter is equivalent to the predicate device in terms of safety, effectiveness and performance.

signed: _____ date: 21-Sep-01

Brett Whiston
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2001

Mr. Brett Whiston
Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place
East Tamaki, Auckland
New Zealand

Re: K002839
End Expiratory Filter, Model RT020
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II (two)
Product Code: 73 CAH
Dated: September 21, 2001
Received: September 25, 2001

Dear Mr. Whiston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Fisher & Paykel HEALTHCARE

[510(k)] Number: K002839

Fisher & Paykel Healthcare Ltd
15 Maurice Paykel Place
East Tamaki
P O Box 14 348
Panmure, Auckland
New Zealand
Telephone: +64-9-574 0100
Facsimile: +64-9-574 0158

21 September, 2001

Fisher & Paykel Healthcare - RT020 End Expiratory Filter

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare RT020 End Expiratory Filter is a Breathing Circuit Bacterial Filter as per 73 CAH, 21 CFR §868.5260. It is intended to remove micro-biological and particulate matter from the gases in a breathing circuit.

The RT020 End Expiratory Filter is intended to be placed at the end of the expiratory limb of a ventilator breathing circuit, connecting to the return port of the ventilator.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002839

✓ Prescription Use
(Per 21 CFR §801.109)